

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of:)	
)	
Manfred BOHN et al.)	Group Art Unit: 1639
)	
Application No.: 09/077,194)	Examiner: Jon D. Epperson
)	
Filed: May 26, 1998)	Confirmation No. 5713
)	
For: USE OF 1-HYDROXY-2-PYRIDONES)	
FOR THE TREATMENT OF)	
SEBORRHEIC DERMATITIS)	

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF UNDER 37 C.F.R. § 41.41

In support of the Appeal Brief filed on December 21, 2007 ("Appeal Brief"), and in reply to the Examiner's Answer ("Answer") dated May 12, 2008, Appellants present this Reply Brief. Appellants wish to clarify their position in light of the Examiner's statements in the Answer. Otherwise, Appellants rely on their arguments as set forth in the Appeal Brief.

I. *Lange* Cannot Be Used to Override the Specification's Written Description

In the Appeal Brief, Appellants explained that organic acid, when used to adjust pH, does not act as an anti-seborrheic agent. Appeal Brief at 13-17. The Examiner alleges, however, that this argument relies on a limitation that is not recited in the claims. Answer at 24. Specifically, the Examiner notes that claim 38 does not recite "a

sole antiseborrheic component” therefore precluding, in the Examiner’s opinion, “any other active component regardless of the nature of the activity.” *Id.* See also Answer at 27 for a similar argument from the Examiner. Appellants explained, however, that the Examiner misinterprets the meaning of claim 38, which indicates that the “active component” is active against seborrheic dermatitis (“SD”). Appeal Brief at 16. Specifically, claim 38 recites “[a] method of treating seborrheic dermatitis in a human patient in need thereof comprising administering to the patient an amount effective for the treatment of seborrheic dermatitis of a single composition, wherein this composition comprises: . . . a sole active component” The preamble of claim 38 clearly connects the treatment of SD with the composition administered to the patient. Thus, claim 38 contemplates a method using a composition in which the described 1-hydroxy-2-pyridone is the sole active component to treat SD. This also applies to the preamble of claim 39 as well.

The Examiner notes that claim 38 does not read “a sole active component with minor amounts of other active ingredients,” but instead recites “a sole active component.” Answer at 25. In making this statement, the Examiner still incorrectly considers organic acid as an active ingredient against SD. Organic acid is not an “active ingredient” as recited in claim 38, which is consistent with the specification’s teaching. Indeed, the specification is the central source for determining whether the written description requirement has been met. Appeal Brief at 13. The specification does no more than instruct the skilled artisan that, when a salt form of the 1-hydroxy-2-pyridone is used in the invention, one should use an organic acid to adjust the pH. The specification does not suggest that the organic acid would be active against SD. This is

not “irrelevant” as the Examiner suggests. Answer at 25. A chemical does not have an antimicrobial effect in all circumstances, such as when it is used in trace amounts as a buffer. Therefore, the antimicrobial effect is not an inherent property of a chemical. For example, a composition of pure bleach can have potent antimicrobial powers, but a composition of very diluted bleach loses its antimicrobial properties. The chemical nature of the bleach itself has not changed in the diluted composition, but its biological effects (i.e., antimicrobial effects) have. The same thing happens when an organic acid is used in for buffering pH in small amounts. The only example in the specification that uses an organic acid is Example 7, and lactic acid, the organic acid used, is only present at 0.51%. Specification at 12. To the contrary, *Lange* uses organic acids at 5%, an order of magnitude larger than that set forth in Appellants’ specification, for their antimicrobial properties. *Lange* at 15. In other words, the Examiner confuses the antimicrobial properties of an organic acid, which may occur only in some circumstances, with an inherent property which must occur in all circumstances. This also applies to the Examiner’s comments at page 28 of the Answer. See “Response 1.” Therefore, the mere use by Appellant of an organic acid for pH buffering is not use of an organic acid for SD treatment or for antimicrobial effects.

Moreover, contrary to the Examiner’s reading of the Appeal Brief, Appellants have not “admitted” that *Lange* makes clear that acids *per se* possess antimicrobial action. Answer at 25. Appellants statements at pages 12 and 13 of the Appeal Brief describe the *Examiner’s* position, not Appellants. Appellants direct the Board’s attention to page 15 of the Appeal Brief, last two lines, concluding that “the entirety of *Lange* does not show that organic acids, *per se*, have antimicrobial activity.” The Examiner’s cite to

page 7 of *Lange*, that “the effect of the antimycotic in phase I as well as phase II is enhanced,” is out of context. Answer at 28. In the preceding paragraph of page 7, *Lange* explains that the alleged “enhancement” stems from the effect that the phase I composition has on the skin to enhance penetration of antimycotics into the skin as introduced in the phase II composition. *Lange*’s teaching here is consistent with its teaching that combining phase I and phase II into one composition would destroy its antimycotic effects. The alleged “enhancement” the Examiner refers to comes from the separate use of the phase I and phase II compositions. As Appellants explain below and in the Appeal Brief, the instant invention contemplates the use of a “single composition.”

Finally, the Examiner contends that “Appellants’ specification and claims do not require the mixing of the two stated shampoos in *Lange* . . . that allegedly destroys inherent physiochemical properties.” Answer at 26. Appellants disagree. Claim 38, for example, recites administering a “single composition.” In order for *Lange* to satisfy this requirement in claim 38, both of *Lange*’s compositions, phase I and phase II, would have to be mixed together into a single composition. As Appellants explained, *Lange* clearly teaches that it is impossible to administer their invention as a “single composition” without losing its beneficial effects. See Appeal Brief at 15; *Lange* at 4 and 11. Contrary to the Examiner’s reading of *Lange*, there is nothing in *Lange* to suggest that the destruction of the antimycotic properties in the phase II composition would only happen with detergents taught in *Lange*. Answer at 28 and 29. *Lange* teaches that “soaps are not well suited for making lower pH products,” and therefore taught away from Appellants’ invention. See Appeal Brief at 15; *Lange* at 4.

In addition, the Examiner's distinction between "antimycotic" and "antimicrobial" effects is a false distinction. Answer at 26. An antimicrobial has negative effects on microbes, which include fungi, as would be known in the art. Thus, antimycotic activity, or activity against fungi, is a form of antimicrobial activity such that a loss of antimycotic activity is a loss of antimicrobial activity.

II. Seborrheic Dermatitis Is Defined By the Specification

The Examiner searches for the "true meaning" of SD, asking "how can the Examiner determine the true meaning of seborrheic dermatitis from the specification as purported when such essential ingredients are missing from the alleged definition?" Answer at 30. As Appellants explained, the specification describes SD as a condition of the scalp that differs from simple dandruff in that it is characterized by "erythema[, a] greater degree of scaling with occasional itching and burning, and by the occurrence of eczematous changes in other body sites." Appeal Brief at 19. During the previous appeal of this application, the Board had no difficulty turning to the specification and concluding that the specification teaches a difference between SD and dandruff, a point that the Examiner has not addressed in the Answer. *Id.* See also, *Ex Parte Bohn Board Decision*, September 15, 2004.

The Examiner's reliance on *Sanfilippo* and "*the Foundation paper*" for alleged characteristics of SD and dandruff is improper. Answer at 30 and 31. Neither of these references is prior art against the claims on appeal. The *Sanfilippo* paper is dated 2006 while "*the Foundation paper*" was downloaded from the International Eczema-Psoriasis Foundation's web site in 2007. The key issue is whether persons of ordinary skill in the art, at the time of the invention, understood SD and dandruff to be separate, distinct

conditions. Notably, the Examiner has also attempted to use the alleged teachings from other references in the rejections on appeal that are not prior art. These references include the *WebMD paper* (downloaded in 2007; Answer at 32 and Advisory Action mailed July 16, 2007 (“Advisory Action”) at 24), *Dreumex* (downloaded in 2005; Answer at 39 and Advisory Action at 20), *Brinkster* (downloaded in 2005, Answer at 40 and Advisory Action at 20), and *Avre* (downloaded in 2005, Advisory Action at 16).

Regarding *Dascalu*, Appellants noted that *Dascalu* does not describe the hyperproliferation of keratinocytes or the presence of “crusted patches” on the skin. Appeal Brief at 21. Also, while *Dascalu* appears to generally describe scaling of the skin, *Dascalu* does not mention the “hyperproliferation of keratinocytes” that is the hallmark of SD (as noted by Dr. Leyden), nor does *Dascalu* teach “oily, yellowish scales,” which result from this condition. *Id.* Thus, *Dascalu* does not describe SD.

III. The Examiner’s Statements Regarding *Lagarde* and *Lange* Do Not Overcome Appellants’ Arguments

The Examiner continues to base his rejection of claims 39 and 61-64 on the incorrect conclusion that claim 39 encompasses more than one active ingredient. Answer at 33. As Appellants explained in detail above and in the Appeal Brief, both claims 38 and 39 contemplate only one active ingredient against SD. Appeal Brief at 23. Regardless of the Examiner’s arguments, the fact remains that *Lagarde* does not teach or suggest non-combination products, i.e., a “single” composition comprising a “sole” active component, or the use of 1-hydroxy-2-pyridones as a sole active component. Indeed, the Examiner attempts to read into *Lagarde* a teaching that is not

there. *Lagarde* fails to disclose each and every element of independent claim 39 and therefore cannot anticipate claim 39 and dependent claims 61-64.

Regarding *Lange*, Appellants noted that in the previous appeal in this application, the Board concluded that *Lange* was not the closest prior art. Appeal Brief at 25. Whether or not the Examiner's supervisor (SPE) and the Group Director signed their approval of the Examiner's use of *Lange* in an anticipation rejection, this rejection disregards the Board's prior assessment of *Lange*. Answer at 34. Even though the Board's decision was unpublished, the facts in this appeal are "on all fours" with the facts in the preceding appeal, so that Board's prior opinion is governing. Claims construction is a question of law, and "previously decided points of law must be followed unless overruled." *Ex parte Holt*, 19 USPQ2d 1211, 1214 (B.P.A.I. 1991). Here the Board made it clear that *Lange* was not the closest prior art and the Examiner must abide by this decision. The Examiner now refers to "new facts/issues [that] were raised in the 1/17/06 non-final Office Action that were not brought to the Board's attention during the first appeal" without explaining what those alleged "new facts/issues" were. Answer at 34. In considering the rejections at issue during the first appeal, the Board considered *Lange* and concluded that it was not the closest prior art, indicating that this reference should not be used as the foundation of an anticipation rejection. Contrary to the Examiner's assumption, Appellants' amendment of claim 39 does not mean that Appellants believed that the rejection was proper. Answer at 35. Therefore, *Lange* is not the closest prior art according to the Board's earlier decision. *Ex Parte Bohn Board Decision*, September 15, 2004.

Finally, the Examiner reasserts his argument that the “claimed limitation of treating seborrheic dermatitis with a ‘single composition’ must not be construed to preclude the application of more than one composition later in time.” Answer at 35. According to the Examiner, the term “comprising” (i.e., a method of treating SD comprising...) does “not preclude the use of additional ingredients in subsequent applications.” Answer at 37. Appellants disagree. The present claims require application of one composition for treatment, not two or more at the time of treatment. Appeal Brief at 25 and 26. See also *Eli Lilly and Co. v. Novo Nordisk A/S*, 1999 WL 1094213, *12 (D. Del. Nov. 18, 1999) (“Holding that “comprising ... two zinc ions” means “not more than two zinc ions.”) For these reasons and the reasons set forth in the Appeal Brief, claims 39 and 62-64 are not anticipated by *Lange*.

IV. The Examiner’s Statements Do Not Establish the Obviousness of the Claims

Responding to Appellants’ arguments concerning the obviousness rejection of claims 38-42, 48, 53-58, and 61-66 based on *Lange*, *FDA*, and *Dascalu* in view of *Green People*, *Avre*, *Dreumex*, *Odds*, and *Brinkster*, the Examiner contends that a pH of 6-8 is neutral. Answer at 39. Appellants disagree. A pH range of 4.5 to 6.5, as recited in claim 38, is acidic, as would be known in the art. With respect to claim 38 and its dependent claims, Appellants explained that *Lange* clearly teaches that one phase containing a detergent and a second phase containing an organic acid cannot be mixed together without loss of effectivity. Appeal Brief at 30. In *Lange*’s words, such a combination is not feasible. *Id.*; *Lange* at 4 and 11. The combined teachings of *FDA*, and *Dascalu* in view of *Green People*, *Avre*, *Dreumex*, *Odds*, and *Brinkster* do not

compensate for *Lange*'s teaching away from the claimed invention as discussed in the Appeal Brief at pages 31 and 32. Clearly, one of ordinary skill in the art "would be discouraged from following the path set out" in the instant invention because *Lange* instructs that it would not work. Answer at 40. Moreover, the alleged teaching in *Lange* that piroctone olamine could be used in a phase II composition does not suggest that piroctone olamine would be functional as an antimycotic in the presence of a surfactant as recited in claim 38. Notably, *Lange*'s phase II compositions are devoid of surfactants such as detergents. *Lange* at 9-11.

According to the Examiner, *Dascalu* "indicates that . . . ciclopiroxolamine would be useful for treating the same disease as seborrheic dermatitis." Answer at 41. Appellants respectfully disagree with the Examiner's summary of this reference. Yet again, the Examiner is leaping from dandruff to SD without any support. Further, *Dascalu*, teaches compositions containing two active ingredients, a cytotoxic agent and an antifungal agent for treating dandruff, which is a different condition from SD. Appeal Brief at 31. Indeed, *Dascalu* does not even address compositions in which a 1-hydroxy-2-pyridone is the sole active ingredient against SD nor does this reference teach the combination of the active ingredient and surfactants all in a single composition even for treatment of dandruff, let alone for the treatment of SD. And, like *Dascalu*, *Lange* also fails to teach a single composition. Instead, *Lange* teaches the use of two separate compositions to provide treatment. Thus, for these reasons and those further articulated in the Appeal Brief, the combination of *Lange*, *FDA*, and *Dascalu* in view of *Green People*, *Avre*, *Dreumex*, *Odds*, and *Brinkster* does not render claims 38-42, 48, 53-58, and 61-66 obvious.

Turning to the obviousness rejection of claims 38-42, 48, and 61-66 over *Verdicchio* in view of *Janniger* and *Dittmar*, the Examiner again incorrectly equates dandruff with SD. Answer at 44 and 49. As Appellants have explained at great length and as the Board has concluded, dandruff and SD are not the same condition. Appeal Brief at 19-21. Moreover, at the time of the invention, it was unclear to persons of ordinary skill in the art as to what causes SD. Appeal Brief at 38. Thus, one cannot conclude that the “causative agent [of dandruff and SD] are so similar” or that “many believed that SD and dandruff were both caused by the same agent.” Answer at 45 and 47. Given that the skilled artisan did not know what caused SD, she would not “immediately recognize that one therapeutic agent could be used to treat both diseases” or reasonably expect that this would be the case, contrary to the Examiner’s reasoning. *Id.* And, as Appellants explained above and in the Appeal Brief, the symptoms of dandruff and SD are not “virtually identical.” Appeal Brief at 19-21. The Examiner’s alleged premise for obviousness is not correct.

In addition, the Examiner’s analysis of the *BMS* case is not correct, especially in the statement, “there seems to be little difference between ‘the human in need thereof’ phrase from *Jansen* and ‘a cancer patient undergoing taxol treatment [i.e. presumably only humans in need thereof undergo such a treatment.]” Answer at 46. In fact, Appellants’ term “the human in need thereof” supports following *Jansen* and not *BMS*. In *BMS*, nothing in the claim referred back to the preamble to breathe life and meaning in the claim, but here, as in *Jansen*, Appellants refer back to the preamble with “the human in need thereof” and therefore the preamble is not just an intended use. Further, *BMS* specifically holds that “new uses of known processes may be patentable.” *Bristol-*

Myers Squibb C. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001). That holding applies to the present case. Accordingly, Appellants maintain that the claims should be construed to require treatment of a human patient for the disease of SD, and not just a symptom associated with the disease. Appeal Brief at 35 and 36.

Finally, Appellants wish to clarify that the “teaching away” argument proposed in the Appeal Brief was in response to the rejection under 35 U.S.C. § 103(a). Appellants are well aware that “teaching away” does not apply to an anticipation rejection. The Examiner, however, asserted this rejection as a combination anticipation or in the alternative obviousness rejection. Having shown that *Verdicchio* does not anticipate claims 38-42, 48, and 61-66 (Appeal Brief at 34), Appellants turned to the obviousness rejection. *Dittmar*’s teaching that other additives can be added to the active ingredient coupled with the assumption that the more active ingredients a product has, the more effective it is, teaches away from a sole active ingredient as recited in the claims. Appeal Brief at 39.

V. Provisional Double Patenting Rejection Is Effectively Moot

The Examiner’s double patenting rejection is provisional, as no patentable subject matter has yet been identified in copending application number 10/606,229. The copending ‘229 application remains under appeal. If patentable subject matter is identified in the ‘229 application, Appellants will file a Terminal Disclaimer in the instant application to render this rejection moot. Appeal Brief at 40.

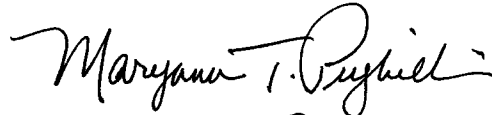
VI. Conclusion

For the reasons set forth above and in the Appeal Brief, claims 38-42, 48, and 61-66 remain allowable and Appellants request reversal of the Examiner's rejections against these claims.

If there are any fees due in connection with filing this brief, which are not enclosed herewith, please charge such fees to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: July 11, 2008

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